PRESCRIBING PATTERNS OF CORTICOSTEROIDS IN PULMONOLOGY DEPARTMENT

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Reg. No. 26107288

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This is to certify that the dissertation work entitled "**PRESCRIBING PATTERNS OF CORTICOSTEROIDS IN PULMONOLOGY DEPARTMENT"** submitted by **Mr. Sanoj Varkey** is a bonafide work carried out by the candidate under the guidance of **Dr. Suchandra Sen,M.Pharm.,Ph.D** and submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfillment for the Degree of **Master of Pharmacy in Pharmacy Practice** at the Department of Pharmacy Practice, KMCH College of Pharmacy, Coimbatore, during the academic year 2011-2012.

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DECLARATION

I do hereby declare that the dissertation work entitled **"PRESCRIBING PATTERNS OF CORTICOSTEROIDS IN PULMONOLOGY DEPARTMENT"** submitted to the Tamil Nadu Dr. M.G.R Medical University, Chennai, in partial fulfillment for the Degree of **Master of Pharmacy in Pharmacy Practice,** was done by me under the guidance of **Dr. Suchandra Sen, M.Pharm., Ph.D** at the department of Pharmacy Practice, KMCH College of Pharmacy, Coimbatore, during the academic year 2011-2012.

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EVALUATION CERTIFICATE

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Examination Center: KMCH College of Pharmacy, Coimbatore

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Internal Examiner **External Examiner**

Convener of Examination

DEDICATED

TO

GOD ALMIGHTY,

MY BELOVED PARENTS AND FRIENDS.

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ABBREVIATIONS

- ACTH : Adrenocorticotropic Hormone
- AR : Allergic Rhinitis
- COPD : Chronic Obstructive Pulmonary Disease
- CRF : Corticotrophin-Releasing Hormone
- DPI : Dry Powder Inhaler
- FEV1 : Forced Expiratory Volume in 1 Second
- GINA : Global Initiative for Asthma
- GOLD : Global Initiative for Obstructive Lung Disease
- ICS : Inhaled Corticosteroids
- IgE : Immunoglobulin E
- INJ : Injection
- LABA : Long-Acting Beta2-Adrenergic Receptor Agonist
- MDI : Metered-Dose Inhaler
- NEB : Nebulizer
- SABA : Short-Acting Beta2-Adrenergic Receptor Agonist
- TNF : Tumor Necrosis Factor
- WHO : World Health Organization

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Introduction

INTRODUCTION

Drug utilization research is an essential part of pharmacoepidemiology as it describes the extent, nature and determinants of drug exposure. Drug use is a complex process. In any country, a large number of socio-cultural factors contribute to the way drugs are prescribed**. (Sachdeva and Patel,2010)**

Drug utilization evaluation can be used for the description of drug use pattern; early signals of irrational use of drugs; interventions to improve drug use; quality control cycle and continuous quality improvement. The principal aim of drug utilization research is to facilitate the rational use of drugs in populations, **(Pandey et al.,2010**). For the individual patient, the rational use of a drug implies the prescription of a well documented drug at an optimal dose, together with the correct information, at an affordable price. Drug utilization research in itself does not necessarily provide answers, but it contributes to rational drug use in important ways as described below.

Drug utilization research can increase our understanding of how drugs are being used as follows.

- It can be used to estimate the numbers of patients exposed to specified drugs within a given time period. Such estimates may either refer to all drug users, regardless of when they started to use the drug, or focus on patients who started to use the drug within the selected period.
- It can describe the extent of use at a certain moment and/or in a certain area. Such descriptions are most meaningful when they form part of a continuous evaluation system, i.e. when the patterns are followed over time and trends in drug use can be discerned.

- Researchers can estimate to what extent drugs are properly used, overused or underused.
- It can determine the pattern or profile of drug use and the extent to which alternative drugs are being used to treat particular conditions.
- It can be used to compare the observed patterns of drug use for the treatment of a certain disease with current recommendations or guidelines.**(WHO,2003)**

This study investigates the prescription pattern of corticosteroids for COPD, Asthma and Allergic Rhinitis; including the demographic variations in their use. The study aims to answer the following questions:

- How does the use of corticosteroids vary with demographic factors, namely age, sex, socioeconomic status and locality of residence?
- What are the different types of steroids prescribed, its dose and route of administration?
- Difference in corticosteroids used in various disorders.
- How does the use of corticosteroids vary with severity of disease?

Corticosteroids are very potent drugs that are known for their anti-inflammatory, anti-proliferative and immunosuppressive effects. Corticosteroids are often called as "steroids"; they greatly improve symptoms and provoke impressive results in different number of conditions, **(Satku, 2006**). Due to their powerful anti inflammatory and immunosuppressive actions, these drugs are being prescribed widely by physicians **(Ankit and Bharat, 2010).**

This study is aimed to measure corticosteroid use in a health facility that will describe drug use pattern and prescribing behavior. The patterns of drug use in a hospital setting need to be monitored intermittently in order to analyze their rationality and to offer feedback to drug prescribers so as to enable and effect suitable modifications in prescribing pattern to increase the therapeutic benefits and reduce adverse effects. **(Kumar et al., 2011)**

Review of Literature

REVIEW OF LITERATURE

Drug utilization audits are qualitative assurance programs to ensure that drugs are used correctly and safely. The nature of such audits can be quantitative or qualitative or combination of both. Quantitative audits are concerned with quantifying various facts of drug therapy use within health care system whereas qualitative audits compare drug use or practice with predetermined standards or criteria**. (Pandey et al., 2010**)

There are only some studies which evaluated trends in prescribing of inhaled corticosteroids for asthma and patterns of prescribing in relation to selected physician characteristics. The percent of physicians prescribing an inhaled corticosteroid increased over time with consistently greater prescribing among specialists. Annual comparisons by specialty groups revealed that specialists prescribed inhaled steroids to a larger proportion of their patients than generalists. (**Allen Ramey et al., 2003)**

Utilization pattern of glucocorticosteroid drugs with special emphasis on their adverse effects in a tertiary care teaching rural hospital, attached to a medical college, showed that dexamethasone dipropionate ,budesonide , and prednisolone were used predominantly in conditions like bronchial asthma, COPD, bronchiectasis, photodermatitis. Most frequent adverse drug reactions observed were muscular weakness and insomnia. Use of glucocorticoid drugs was found appropriate and as per standard guidelines and current protocol of prescribing glucocorticoid drugs. It was also found that there is over prescribing of the drugs to the patients. So the special attention of all doctors and clinical pharmacists is needed to work together to establish a rational, and practical protocol for clinical conditions. **(Ankit and Bharat, 2010)**

A study was carried out to find out prescribing pattern of corticosteroids in dermatology department of a tertiary care teaching hospital. The study revealed that

topical corticosteroids of very potent groups were commonly prescribed and prescribing information was adequate in majority of the cases. This report was aimed for the benefit of the patients, providing feed back to the prescribers and desirable in rationalizing prescribing practices**. (Kumar et al., 2011)**

Inhaled corticosteroids (ICS) are more effective in COPD patients when used with Long-Acting Beta2-Adrenergic Receptor Agonist than with Short-Acting Beta2-Adrenergic Receptor Agonist. Adding long-acting beta agonists to inhaled corticosteroids has been associated with beneficial effects in COPD patients in randomized controlled trials and observational studies. However ,it is not known whether adding short-acting beta agonists to ICS instead of will be similarly effective in COPD. The effectiveness of combination therapies involving ICS with LABA versus ICS with SABA in reducing risk of re-hospitalization or death among COPD patients within a year of discharge from a first COPD hospitalization was studied **(Bettoncelli et al., 2005).**

In a study, on the corticosteroid-prescribing patterns of primary care sports medicine physicians to look for common indications. Fifty-eight of the physicians reported prescribing oral corticosteroids for musculoskeletal injuries. Prednisone was the corticosteroid prescribed most of the physicians. The average prescription length was 7 days. One half of the physicians tapered the dose. The most common starting dose was 60 mg. Despite little evidence to support their use, primary care sports medicine physicians commonly prescribe corticosteroids**. (Kimberly, et al., 2002)**

Topical corticosteroids are widely used in the treatment of skin diseases. Pattern of topical corticosteroids prescribing and the relation of patient and prescriber attributes to the type of corticosteroid preparation prescribed have been studied and found that

dermatologists were more likely to prescribe very high potency steroids than were other physicians. Physicians other than dermatologists were more likely than dermatologists to prescribe combination agents containing moderate-or high-potency topical corticosteroids and an anti infective agent. The pattern of topical corticosteroid prescribing is substantially different for dermatologists and other physicians. These differences may reflect differences in severity or complexity of the disease or differences in prescribing habits**. (Stem et al.,1996)**

A study was carried out to find comparative cost-effectiveness of a fluticasone-propionate/salmeterol combination versus anticholinergics as initial maintenance therapy for chronic obstructive pulmonary disease. In this retrospective study observational sample of COPD patients ,initiating treatment with fluticasone-propionate/salmeterol combination was associated with significantly better clinical and economic outcomes compared with short and long-acting anticholinergic therapy. Consistent with the goal of preventing and reducing exacerbations advocated by global guidelines, the finding suggest that initiation of maintenance treatment with fluticasone-propionate/salmeterol combination may afford clinical benefits at a lower cost than anticholinergic treatment. **(Dalal et al.,2010)**

Another study investigated the pattern of use of medications for asthma in Australia including the demographic variation in their use. In the population, use of both inhaled corticosteroids and long-acting beta agonists increased with age. Use of inhaled corticosteroids and long acting beta agonists was slightly higher in females when all ages were combined. Many people for whom asthma management guidelines would recommend using inhaled corticosteroids were not using them regularly. At the same

time, most inhaled corticosteroids that were dispensed to adults were in the strongest formulation, which may add to the risk of harmful side effects**. (Ampon et al., 2006)**

A study carried out to assess the prescription patterns of asthma medication for children revealed that in general practice the number of prescriptions per child issued for asthma is relatively low. Continuous medication with a bronchodilator and/or a corticosteroid was prescribed in children. Asthma medications other than bronchodilators or corticosteroids were prescribed relatively low. One in 20 children was prescribed bronchodilators only continuously, indicating room for improvement.**(Uijen et al., 2011)**

Endogenous corticosteroids are a class of steroid hormones that are produced in the adrenal cortex. Corticosteroids are involved in a wide range of physiologic systems such as stress response, immune response and regulation of inflammation, carbohydrate metabolism, protein catabolism, blood electrolyte levels, and behavior. The principal adrenal steroids are the glucocorticoids and mineralcorticoids. In humans, cortisol (hydrocortisone) is the main glucocorticoid and aldosterone is the main mineralocorticoid**. (Goodman and Gilman ,2006).**

GLUCOCORTICOIDS

Adrenal steroids are synthesized and released by Adrenocorticotropic Hormone, which is secreted from the anterior pituitary gland. Adrenocorticotropic Hormone secretion is regulated partly by CRF derived from the hypothalamus and partly by the level of glucocorticoids in the blood. **(Rang and dale, 2005)**

- Action on the mediators of inflammatory and immune responses: These include:
- Decreased production of prostanoids owing to decreased expression of cyclooxygenase-2

- Decreased generation of cytokines-IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-8, TNF-γ and cell adhesion factors , granulocyte-macrophage colony-stimulating factor through inhibition of transcription of the relevant genes
- Reduction in the concentration of complement components in the plasma
- Decreased generation of induced nitric oxide
- Decreased histamine release from basophils
- Decreased IgG production**(MacIntyre,2006)**

MINERALOCORTICOIDS

Mineralocorticoid is aldosterone, which is produced in the outermost of the three zones of the adrenal medulla, the zona glomerulosa. Its main action is to increase Na^+ reabsorption by an action on the distal tubules in the kidney, with concomitant increased excretion of K^+ and H^+. An excessive secretion of mineralocorticoids , causes marked Na^+ and water retention with resultant increase in the volume of extracellular fluid, hypokalemia, alkalosis and hypertension. A decreased secretion, as in Addison's disease, causes increased Na^+ loss. The control of the synthesis and release of aldosterone depends mainly on the electrolyte composition of the plasma and on the angiotensin II system. Low plasma Na^+ or high plasma K^+ concentrations affect the zona glomerulosa cells of the adrenal directly, stimulating aldosterone release. Depletion of body Na^+ also activates the renin-angiotensin system. One of the effects of angiotensin II is to increase the synthesis and release of aldosterone. **(Rang and dale,2005)**

USE OF CORTICOSTEROIDS

The use of corticosteroids started some 50 years ago. Being very powerful anti-inflammatory agents, they were described as impressive drugs as they not only improved

certain clinical conditions, but also conferred a subjective sense of well-being. Corticosteroids have been used commonly in the fields of rheumatology, orthopaedics, dermatology, oncology, respiratory medicine, ENT and ophthalmology. Endocrinology utilizes corticosteroids for hypoadrenalism and tapering regimes in hypothalamic-pituitary adrenal axis suppression. While powerful as anti-inflammatory agents, these medications have a host of systemic effects which are harmful to the patient. Hence, care should be exercised in the indications, route of administration and duration of treatment. The latest development towards greater safety of corticosteroids usage with preservation of full efficacy is channeled at the glucocorticoid receptor so that reduced potency in side effects is possible. These new insights may pave the way for novel, safer therapies that retain the efficacy of currently prescribed steroids. **(Ankit and Bharat .,2010)**

Steroids can be prescribed as:

- Topical steroids
- Intranasal steroids
- Inhaled corticosteroids
- Steroid ear and eye drops
- Intra-articular steroid injections
- Oral steroids **(Satku,2006**)

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Chronic obstructive pulmonary disease (COPD) constitutes an important public health issue, with a high prevalence and global morbidity and mortality **(Miguel-Dı´ez et al., 2011)**. COPD is a progressive inflammatory disease affecting the airways of the lungs along with irreversible airflow obstruction **(MacIntyre, 2006).** It can be classified into emphysema and chronic bronchitis. According to the World Health Organization (WHO), the disease affects 210 million people worldwide and it mainly occurs in about

10% of the population above the age of 40 years. In 1990 the sixth commonest global cause of death was COPD, currently fourth in developed countries and by 2020 it is expected to rise to third place globally **(Suissa and Barnes , 2009**).

If the disease is prominent in the proximal airways, symptoms of cough and phlegm predominate (chronic bronchitis). Similarly, if the disease is prominent in the distal small-airway regions of the lung, there may be concomitant alveolar destruction and the sensation of dyspnea may predominate. The most common cause of COPD is tobacco smoke exposure, although a small percentage of COPD patients are never-smokers and are thought to develop chronic airway inflammation and alveolar destruction from genetically determined impaired airway defenses (**MacIntyre, 2006**) .In the treatment regimen of COPD apart from inhaled beta agonists and anticholinergics, corticosteroids can also play a important role.

The management guidelines of COPD recommend drug treatment in the form of short-acting inhaled bronchodilators, followed by long-acting agents in patients with persistent symptoms. The addition of inhaled corticosteroids is indicated for patients with severe or very severe COPD (FEV_1>50% of the reference value) and also in repeated exacerbations, since these drugs have been shown to decrease the number of exacerbations and improve both quality of life and lung function in these individuals **(Miguel-Dı´ez et al., 2011**). In addition, a recent study in patients with FEV_1 >60% of the reference value , has confirmed the positive impact of combining inhaled glucocorticoids and long-acting beta –adrenergic agonists upon these same parameters (**Calverley et al., 2007)** The rest of COPD patients cannot benefit from inhaled corticosteroids, and may experience side effects from their use.

Although cigarette smoking is the major risk factor for COPD, occupational exposure and environmental pollutants are also implicated. Genetic factors also play an important in determining which exposed individuals will develop COPD. A significant example is alpha$_1$-antitrypsin deficiency. In susceptible individuals, exposure to noxious gases or particles can result in chronic inflammation with tissue injury, ineffective repair and structural changes. These changes occur in central and peripheral airways, lung parenchyma and pulmonary vasculature. Subsequent to these changes, hypoxemia and alveolar hypoventilation can occur.Increased inflammation, often triggered by infection, may result in further physiological comprise and clinical exacerbations.

By altering gene transcription and protein synthesis inhaled corticosteroids reduce airway inflammation. COPD is relatively corticosteroid resistant possibly because it is predominantly a neutrophilic inflammatory disease. Guidelines recommend inhaled corticosteroids in patients with frequent exacerbations or those who have severe disease (FEV_1<50%) and remain symptomatic despite inhaled long-acting bronchodilator use. Clinical and physiological effects may include a reduction in symptoms and exacerbation frequency, and improvement in health status and FEV_1. Some trials of inhaled corticosteroids have raised questions about data analysis and an absence of true intention-to-treat analysis in some of the studies. Further analysis of recent studies may be needed to clarify the true role of inhaled corticosteroids in COPD. Overall, there are few data about back-titrating of corticosteroids (**Malipatil and McDonald , 2009)** Ten to thirty per cent of the total dose of inhaled corticosteroids is systemically absorbed because of absorption from the lung. Quantifying the risk of systemic adverse effects is challenging given confounding factors such as co morbidities, oral corticosteroid use and the systemic effects of COPD. This balance of benefits versus adverse effects may be

important in the elderly who are at risk of co morbidities. Local adverse effects include oral candidiasis and dysphonia.

ALLERGIC RHINITIS

Allergic rhinitis (AR) is a common disease affecting large population and may cause significant social and economic impact if they are not managed appropriately. Allergic rhinitis can be defined as the inflammation of the nasal mucosa, induced by exposure to allergens after sensitization; triggered by an immunoglobulin E-mediated inflammatory response that can result in chronic or recurrent symptoms. Allergic rhinitis may be also called as seasonal allergic rhinitis. Seasonal rhinitis occurs in response to specific allergens usually present at predictable times of the year, during plants' blooming seasons. Seasonal allergens include pollen from trees, grasses, and weeds. Perennial allergic rhinitis is a year-round disease caused by nonseasonal allergens, such as house-dust mites, animal dander, and molds, or more allergic sensitivities. **(McCroryet al., 2003)**

Allergic rhinitis is always associated with several other serious medical conditions, including asthma, rhino-sinusitis, otitis media, nasal polyposis, respiratory infections, and orthodontic malocclusions (**Plaut and Valentine, 2005).** The development of allergic rhinitis is determined by genetics, allergen exposure, and the presence of risk factors. A family history of allergic rhinitis, atopic dermatitis, or asthma suggests that rhinitis is allergic. Allergen exposure is another necessary factor. For allergic rhinitis to occur, an individual must be exposed over time to a protein that elicits the allergic response in that individual **(Marshall et al., 2001).**

Allergic reactions in the nose are mediated by antigen-antibody responses, during which allergens interact with specific IgE molecules bound to nasal mast cells and

basophils. In allergic people, these cells are increased in both number and reactivity. During inhalation, airborne allergens enter the nose and are processed by lymphocytes, which produce antigen-specific IgE, thereby sensitizing genetically predisposed hosts to those agents. Upon nasal re-exposure, IgE bound to mast cells interacts with airborne allergen, triggering release of inflammatory mediators. **(Wilson et al., 2000**).

Bronchitis can develop as a result of allergic rhinitis because of excess fluid in the chest. Bronchitis is an infection in the lungs that causes the airways to swell, causing asthma-like symptoms, such as difficulty in breathing, wheezing and shortness of breath.

Topical glucocorticoids, including beclomethasone, budesonide, flunisolide, fluticasone and triamcinolone, *c*an be highly effective with minimal side effects, particularly if treatment is instituted immediately prior to the allergy season. Topical glucocorticoids can be administered twice daily (beclomethasone and flunisolide) or even once daily (budesonide, mometasone, fluticasone, and triamcinolone).

Nasal steroids are an excellent choice for treating perennial rhinitis, and can be useful in seasonal rhinitis, especially if begun in advance of symptoms**. (Weiner et al., 1998**) Nasal steroids appear to be effective with minimal adverse effects. Some believe that nasal steroids should be recommended as initial therapy over antihistamines because of their high level of efficacy when used properly and along with avoidance of allergens**.(Quintiliani,1996)** Multiple mechanisms are involved with the effects of nasal steroids on the nasal mucosa: reducing inflammation by reducing mediator release, suppressing neutrophil chemotaxis, reducing intracellular edema, causing mild vasoconstriction, and inhibiting mast cell-mediated late-phase reactions.(**Mehle , 2003)** Topical steroids produce only minor adverse effects, most commonly sneezing, stinging, headache, and epistaxis. Despite concerns about safety of systemic steroids, nasal

steroids have been found to have no significant association with hypothalamic–pituitary axis suppression, cataract formation, glaucoma, or bone mineral density changes in the doses used for allergic rhinitis. **(Adams et al., 2002**)

ASTHMA

Asthma is a chronic disease of the airway inflammation and airflow obstruction characterized by symptoms such as wheezing, breathing difficulty, chest tightness and cough along with bronchial hyper-responsiveness. In India 3-5% and 3-11% of the pediatric and adult population respectively is affected by asthma**.(Pandey et al., 2010)**

Long term treatment is required for the effective management of the disease. Asthma is associated with airway inflammation, airway hyper-reactivity, and acute bronchoconstriction. Glucocorticoids do not directly relax the airway smooth muscles and thus have little effect on acute bronchoconstriction. The anti-inflammatory effects of glucocorticoids in asthma include modulation of cytokine and chemokine production; inhibition of eicosanoid synthesis; marked inhibition of accumulation of basophils, eosinophils, and other leukocytes in lung tissue; and decreased vascular permeability.

(MacIntyre,2006)

Systemic Glucocorticoids are used for acute asthma exacerbations and chronic severe asthma. Significant doses of glucocorticoids (*e.g.*, 40 to 60 mg prednisone or equivalent daily for 5 days; 1 to 2 mg/kg per day for children) are often used to treat acute exacerbations of asthma. Previously, alternate-day therapy with oral prednisone was employed commonly in persistent asthma. Now most patients with asthma are better treated with inhaled glucocorticoids.. There are currently five glucocorticoids available for inhalation therapy: beclomethasone, dipropionate, triamcinolone acetonide, flunisolide, budesonide, and fluticasone propionate. The newer, highly potent drugs

(*e.g.*, fluticasone, flunisolide, and budesonide) can be effective with as little as one or two puffs administered twice or even once daily. Important variables that influence the effective dose include the severity of disease, the particular steroid used, and the device used for drug delivery, which determines the actual quantity of drug delivered to the lungs.**(Goodman and Gilman,2006)**

Methodology

METHODOLOGY

Aim

To analyze the prescribing patterns of corticosteroid drugs in the pulmonology department of a tertiary care hospital.

Study design

It was a prospective study.

Study setting

The study was conducted in the Department of Pulmonology and Sleep Medicine Kovai Medical Center and Hospital in Coimbatore, Tamil Nadu.

Study period

The study was conducted over a period of six months from June 2011 to December 2011.

Study criteria

Inclusion criteria

Patients with COPD, asthma and allergic rhinitis, attending the pulmonology clinic who receives corticosteroid drugs as their treatment plan.

Exclusion criteria

Patients with COPD, asthma and allergic rhinitis, attending the pulmonology clinic who are not receiving corticosteroids.

Sources of data

The data was collected from various sources such as patient's case reports and treatment charts.

Study protocol

Patients who met the study criteria were identified. Demographic details, different corticosteroids prescribed and their dose and route of administrations were noted.

Severity of the asthma and COPD were classified based on GINA and GOLD guidelines respectively.

Severity of disease

The GOLD and GINA guidelines for assessing the severity of COPD and asthma respectively, were used to assess the same.

Statistical analysis

Demographic characteristics have been expressed as percentages. Analysis of the relationship between variables was compared by using chi square test and the p value ≤ 0.05 was taken to be significant. All statistical data was assessed by using SPSS (v-16.0).

Results

RESULTS

In this Prospective study, the prescribing patterns of corticosteroid drugs was evaluated in a total of 108 prescriptions in the pulmonology department in a tertiary care hospital, during the period June 2011 to December 2011.

Among corticosteroid prescriptions, 58 (53.7%) were males and 50(46.3%) were females (Table 1, Figure 1). Highest number of prescriptions (25 out of 108) were belonging to the age group of 60-69 years (23.14%) and lowest number of prescriptions (4 out of 108) were belonging to the age group of 10-19 years (3.7%). (Table 2, Figure 2).

Among total corticosteroid prescriptions, 23 (21.3%) were inpatients and 85(78.7%) were outpatients (Table 3, Figure 3).The total study population were categorized into four group on the basis of diagnosis. It was given as Asthma, COPD, Allergic Rhinitis & Allergic Rhinitis + Asthma with percentage population of 37.96%, 33.33%, 19.44% & 9.25% respectively. (Table 4, Figure 4).

Most of the prescriptions containing corticosteroid were made for patients coming from urban and industrial polluted areas like Coimbatore (35.18%) and Tirupur (22.22%). (Table 5, Figure 5). Out of 108 prescriptions, 84 prescriptions were given to patients who were free from co-morbidity. Remaining 24 patients were diagnosed with more than one disease (co-morbid condition). (Table 6, Figure 6).

Most common route of administration was dry powder inhaler (67.2%) followed by MDI (16.8%), Nasal spray (10.4%), and Oral (5.6%) respectively. (Table 7, Figure 7). Most commonly prescribed drug was Budesonide + Formoterol (78.4%)combination whereas Budesonide(2.4%) alone was less commonly prescribed. (Table 8, Figure 8).

Budesonide + Formoterol 200 mcg combination was given in 37 prescriptions and 400 mcg was given in 61 prescriptions(Table 9, Figure 9). Budesonide 100 mcg containing 0ne prescription out of 108 prescriptions and Budesonide 200 mcg containing two prescriptions in the total prescriptions(Table 10, Figure 10).Oral route of prednisolone 20 mg and 30 mg containing 3 and 4 prescriptions respectively.(Table 11, Figure 11). Fluticasone+Salmeterol 50,100 and 200 mcg combination containing 1,1 and 2 prescriptions respectively. (Table 12, Figure 12).

Median route of administration in Asthma, COPD and Allergic Rhinitis +Asthma prescription was dry powder inhaler. The most prominent route of administration was nasal spray in Allergic Rhinitis prescriptions. (Table 13). Median drug of administration in Asthma , COPD and Allergic Rhinitis +Asthma prescription was Budesonide + Formoterol - 36(87.80%) , 35(97.22%), 8(80%) respectively. The most prominent drug of administration in Allergic Rhinitis was Mometasone furoate 13(61.90%)(Table 14, Figure 14).

Budesonide + Formoterol 200 mcg combination was prescribed in 5 and 400 mcg was prescribed in 31 of the total 41 Asthma prescriptions. (Table 15, Figure 15).

Our study revealed that majority of the COPD patients, were smoker (52.77%) and 16.66% had a history of smoking (Table 16, Figure 16).Eleven(11) prescriptions had Budesonide + Formoterol 200 mcg and 24 prescription had Budesonide + Formoterol 400 mcg in the total 36 COPD prescriptions. (Table 17, Figure 17).Oral route of prednisolone 20 mg containing two prescriptions and prednisolone 30 mg containing three prescriptions in the total 36 COPD prscriptions. (Table 18, Figure 18).

The most prominent Allergic Rhinitis drug was Budesonide + Formoterol 200 mcg combination(73.68%) in 21 Allergic Rhinitis prescriptions. (Table 19, Figure 19).

Allergic Rhinitis +Asthma prescriptions had Budesonide + Formoterol 200 mcg combination in 3 and Budesonide + Formoterol 400 mcg combination in 5 of the total 21 prescriptions. (Table 20, Figure 20). One each prescription of Budesonide 100 mcg and Budesonide 200 mcg were prescribed in the total Allergic Rhinitis +Asthma prescriptions(n=10)(Table 21, Figure 21).

Most common drug prescribed to IP patients was Budesonide + Formoterol combinations 43.33% and less commonly prescribed drug was Fluticasone+Salmeterol 3.33%.(Table 22, Figure 22).Most general route of administration was Nebuliser(33.33%) and oral route of administration was less commonly prescribed(10%). (Table 23, Figure 23).

In the study population, we found a significant relationship between age ($p<0.007$), gender ($p<0.016$), locality of residence ($p<0.023$) & socioeconomic status ($p<0.016$) and prescribing patterns of corticosteroids.(Table 24, Figure 24).There was a significant relationship with severity of disease such as COPD ($p<0.008$) and Asthma ($p<0.011$) and the prescribed corticosteroids. (Table 25, Figure 25).

Tables & Graphs

TABLES AND GRAPHS

TABLE 1 : Gender wise distribution of total prescriptions.

Sl. No	Gender	No. of prescriptions	Percentage (%)
1.	Male	58	53.7
2.	Female	50	46.3

FIGURE 1 : Gender wise distribution of total prescriptions.

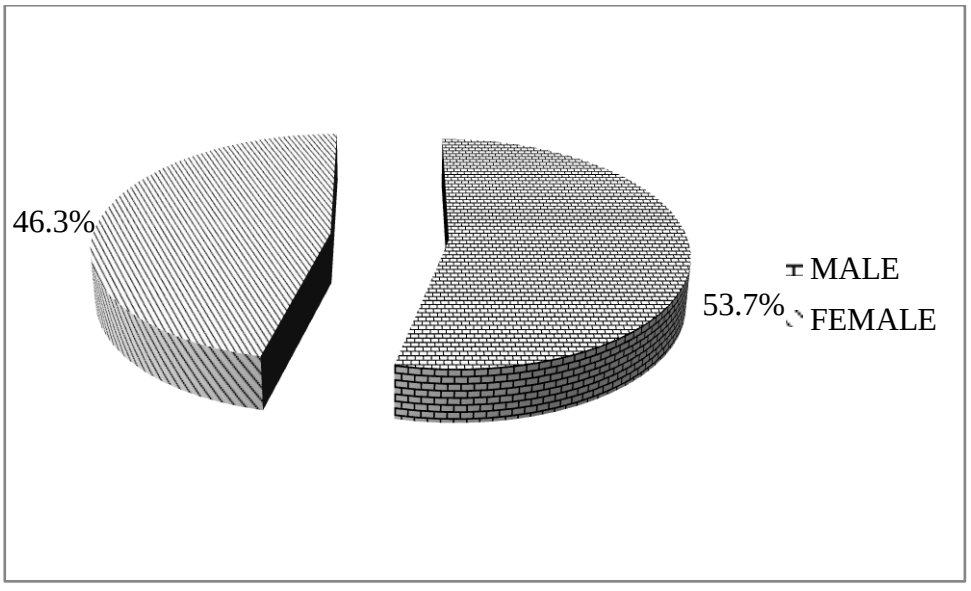


TABLE 2 : Age wise distribution of the total prescriptions.

Sl. No	Age	No. of prescription	Percentage (%)
1.	10-19	4	3.7
2.	20-29	6	5.55
3.	30-39	20	18.51
4.	40-49	23	21.29
5.	50-59	18	16.66
6.	60-69	25	23.14
7.	70-79	12	11.11

FIGURE 2 : Age wise distribution of the total prescriptions.

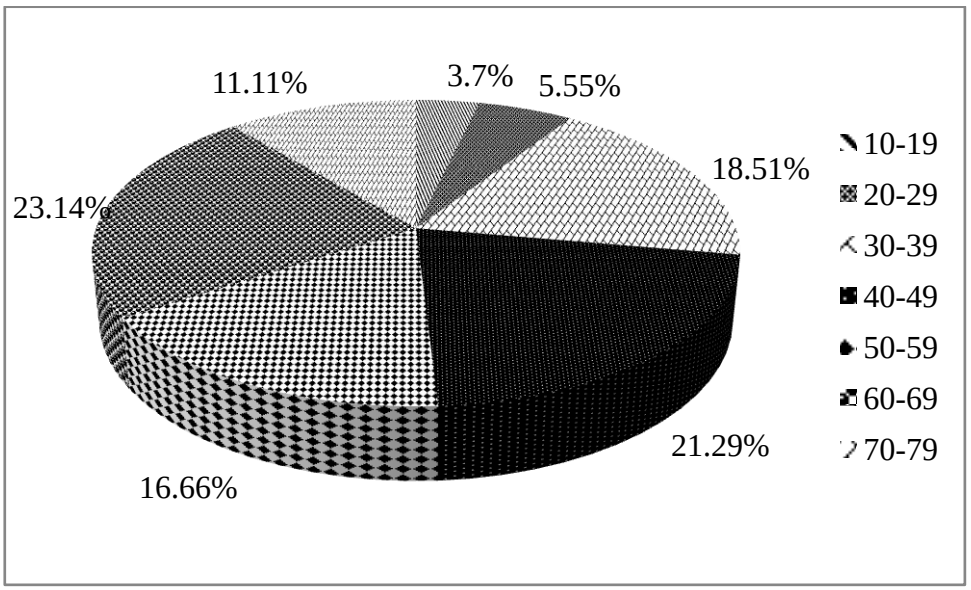


TABLE 3 : Distribution of the total prescriptions on the basis of inpatients(IP) and out patients(OP).

Sl. No	IP/OP	No. of prescriptions	Percentage (%)
1.	IP	23	21.3
2.	OP	85	78.7

FIGURE 3 : Distribution of the total prescriptions on the basis of inpatients(IP) and out patients(OP).

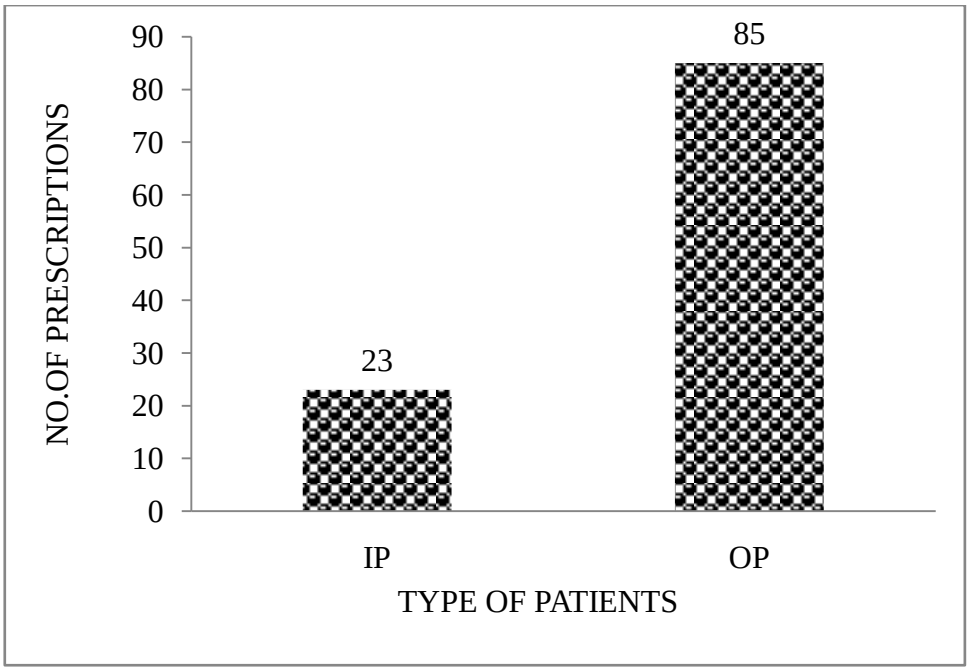


TABLE 4 : Disease wise distribution of the total prescriptions.

Sl. No	Disease	No. of prescriptions	Percentage (%)
1.	COPD	36	33.33
2.	AR	21	19.44
3.	Asthma	41	37.96
4.	AR + Asthma	10	9.25

FIGURE 4 : Disease wise distribution of the total prescriptions.

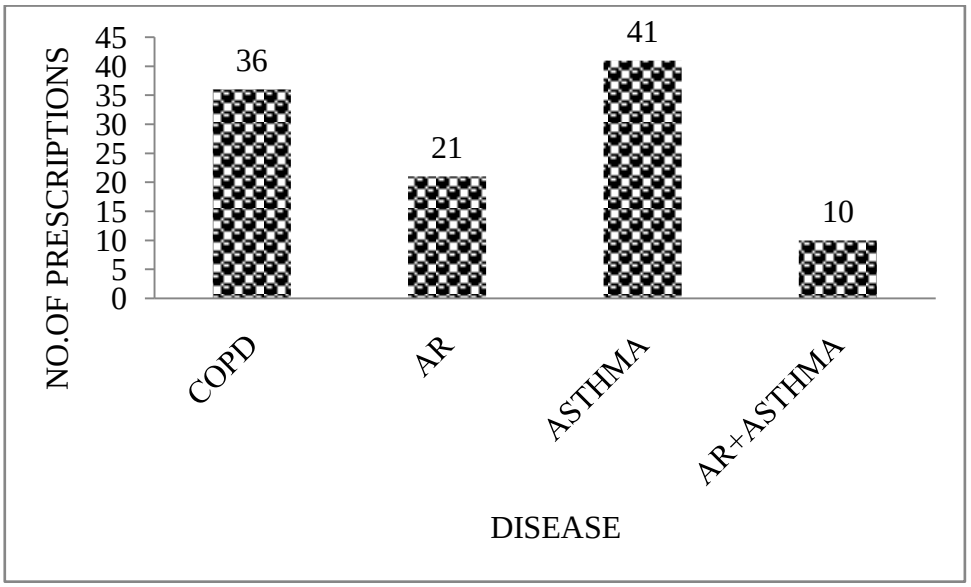


TABLE 5 : Distribution of the prescriptions on the basis of place of residence of the patients.

Sl. No	Locality	No. of prescription	Percentage (%)
1.	Coimbatore	38	35.18
2.	Erode	9	8.33
3.	Dindugal	9	8.33
4.	Karur	5	4.62
5.	Salem	9	8.33
6.	Palakkad	8	7.4
7.	Tirupur	24	22.22
8.	Namakkal	6	5.55

FIGURE 5 : Distribution of the prescriptions on the basis of place of residence of the patients.

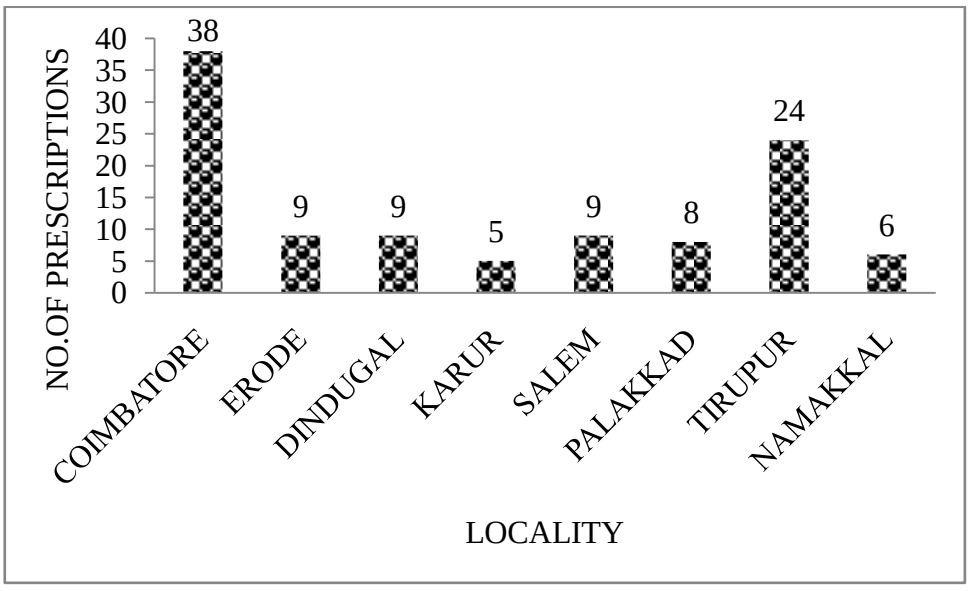


TABLE 6 : Co-morbidity wise distribution of the total study population.

Sl. No	No. of co-morbidity	No. of prescription	Percentage (%)
1.	No disease	84	77.77
2.	1	15	13.88
3.	2	6	5.55
4.	3	2	1.85
5.	>3	1	.92

FIGURE 6 : Co-morbidity wise distribution of the total study population.

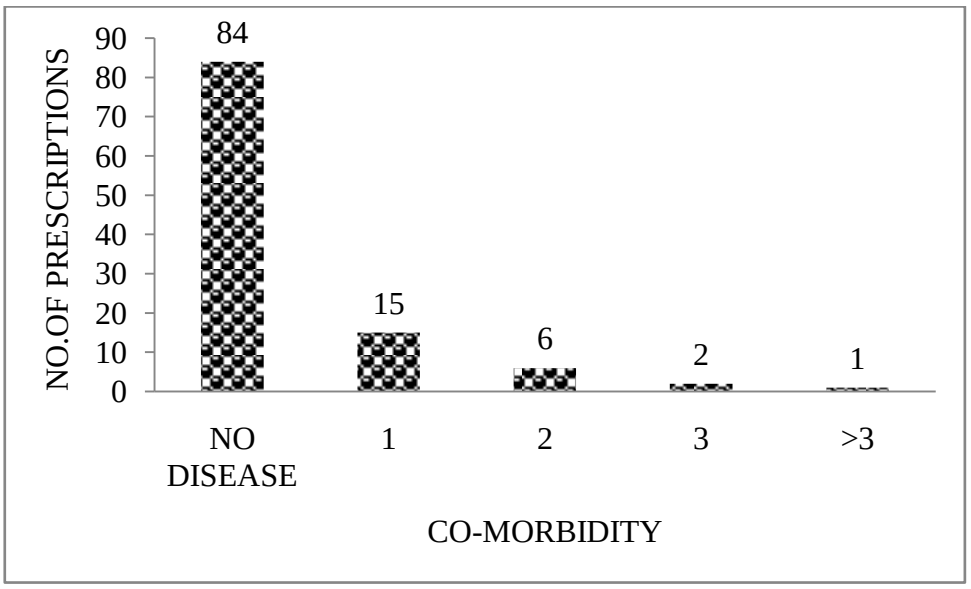


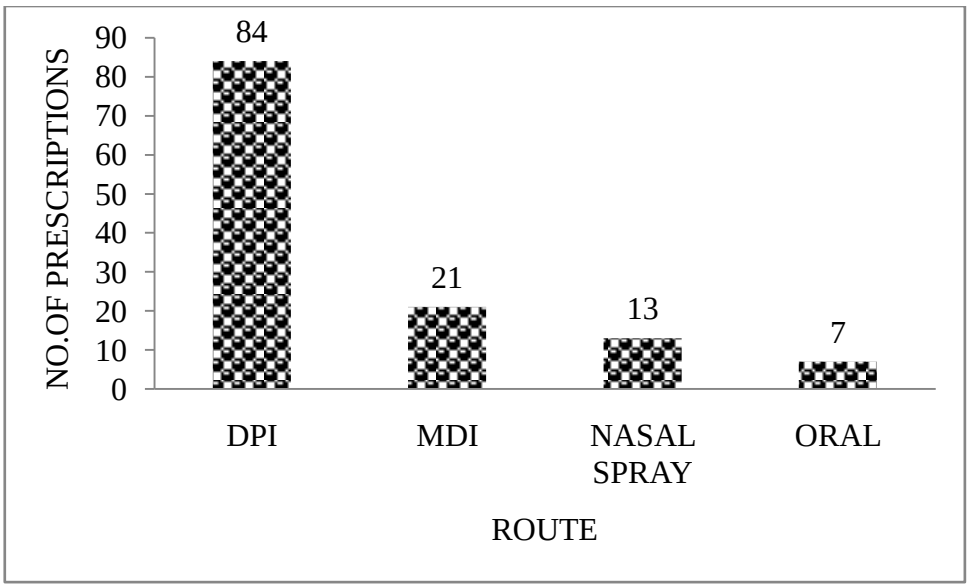
TABLE 7 : Distribution of the total prescriptions on the basis of the route of administration of the corticosteroids.

Sl. No	Route	No, of prescriptions	Percentage (%)
1.	DPI	84	67.2
2.	MDI	21	16.8
3.	Nasal Spray	13	10.4
4.	Oral	7	5.6

DPI - Dry Powder Inhaler

MDI - Metered Dose Inhaler

FIGURE 7 : Distribution of the total prescriptions on the basis of the route of administration of the corticosteroids.



DPI - Dry Powder Inhaler

MDI - Metered Dose Inhaler

TABLE 8 : Corticosteroids prescribed and their frequency in the study population.

Sl. No	Drug	No, of prescriptions	Percentage (%)
1.	Budesonide+Formoterol	98	78.4
2.	Budesonide	3	2.4
3.	Fluticasone+Salmeterol	4	3.2
4.	Mometasone furoate	13	10.4
5.	Prednisolone	7	8.6

FIGURE 8 :Corticosteroids prescribed and their frequency in the study population.

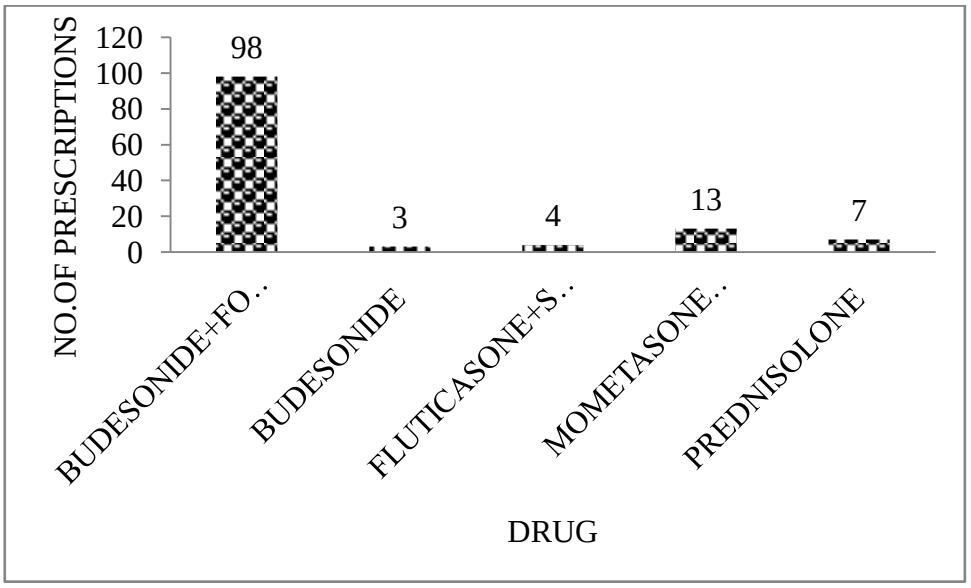


TABLE 9 : Frequency of prescriptions in different doses of Budesonide in Budesonide + Formoterol combination(n=98).

Sl. No	Budesonide+Formoterol (mcg)	No. of prescriptions	Percentage (%)
1.	200	37	37.76
2.	400	61	62.24

FIGURE 9 : Frequency of prescriptions in different doses of Budesonide in Budesonide + Formoterol combination(n=98).

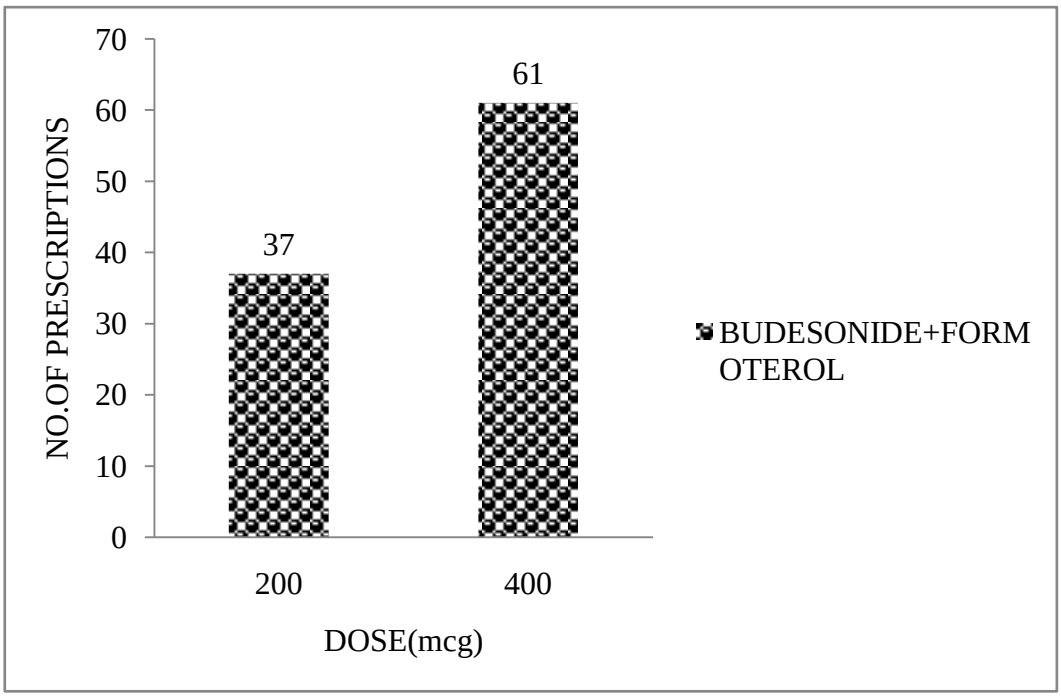


TABLE 10 : Frequency of prescriptions under different doses of Budesonide(n=3).

Sl. No	Budesonide (mcg)	No. of prescriptions	Percentage (%)
1.	100	1	33.33
2.	200	2	66.66

FIGURE 10 : Frequency of prescriptions under different doses of Budesonide(n=3).

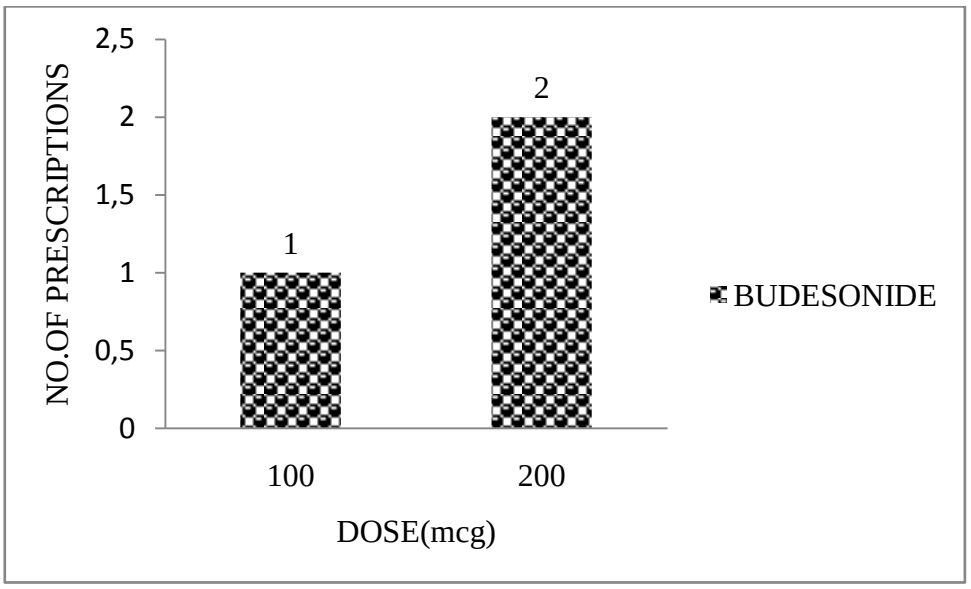


TABLE 11 : Frequency of prescriptions under different doses of Prednisolone(n=7).

Sl. No	Prednisolone (mg)	No. of prescriptions	Percentage (%)
1.	20	3	42.85
2.	30	4	57.14

FIGURE11: Frequency of prescriptions under different doses of Prednisolone(n=7).

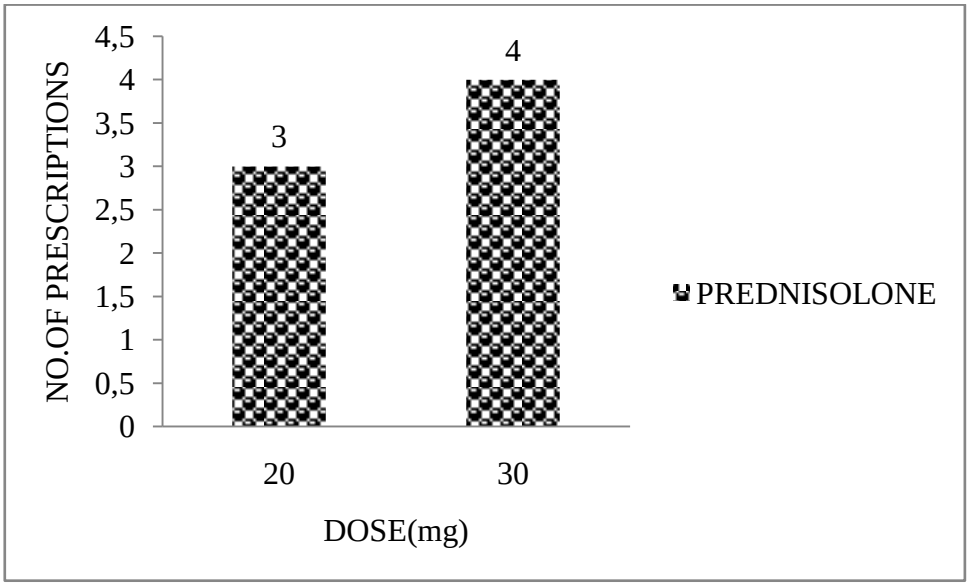


TABLE 12 : Frequency of prescriptions in different doses of Fluticasone in Fluticasone + Salmeterol combination(n=4).

Sl. No	Fluticasone+Salmeterol (mcg)	No. of prescriptions	Percentage (%)
1.	50	1	25
2.	100	1	25
3.	200	2	50

FIGURE 12 : Frequency of prescriptions in different doses of Fluticasone in Fluticasone + Salmeterol combination(n=4).

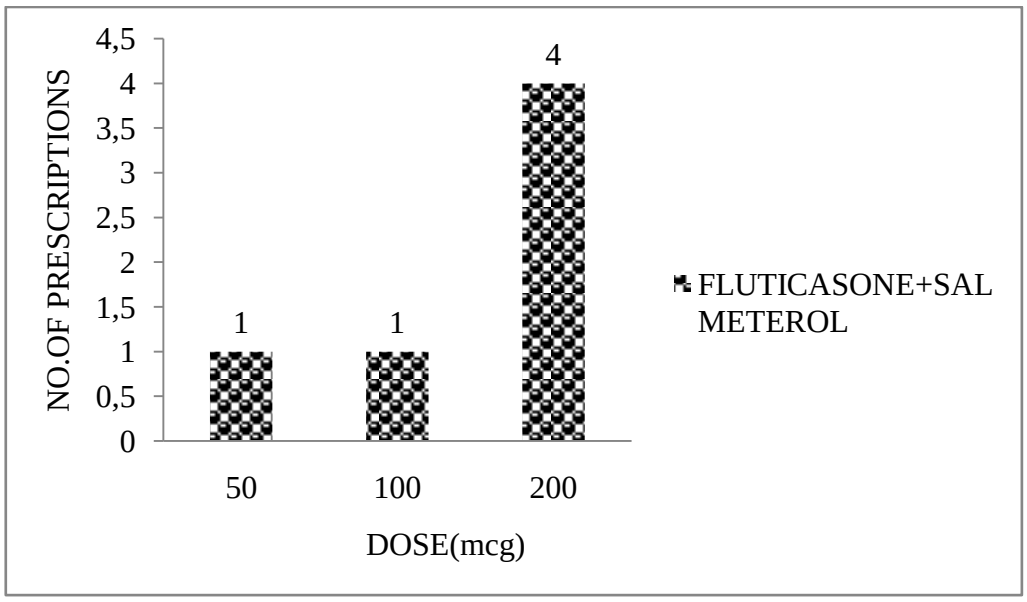


TABLE 13 : Median route of administration in the different disease conditions in the total prescriptions.

Sl. No	Disease(No. of prescriptions)	Median Route	No.of prescriptions.	Percentage (%)
1.	Asthma(41)	DPI	33	80.48
2.	COPD(36)	DPI	21	58.33
3.	AR+Asthma(10)	DPI	6	60
4.	AR(21)	Nasal Spray	13	61.9

TABLE 14 : Median drug of administration in the different disease conditions in the total prescriptions.

Sl. No	Disease(No. of prescriptions)	Median Drug	No.of prescriptions	Percentage(%)
1.	Asthma(41)	Budesonide+Formoterol	36	87.8
2.	COPD(36)	Budesonide+Formoterol	35	97.22
3.	AR+Asthma(10)	Budesonide+Formoterol	8	80
4.	AR(21)	Mometasone furoate	13	61.9

FIGURE 14 : Median drug of administration in the different disease conditions in the total prescriptions.

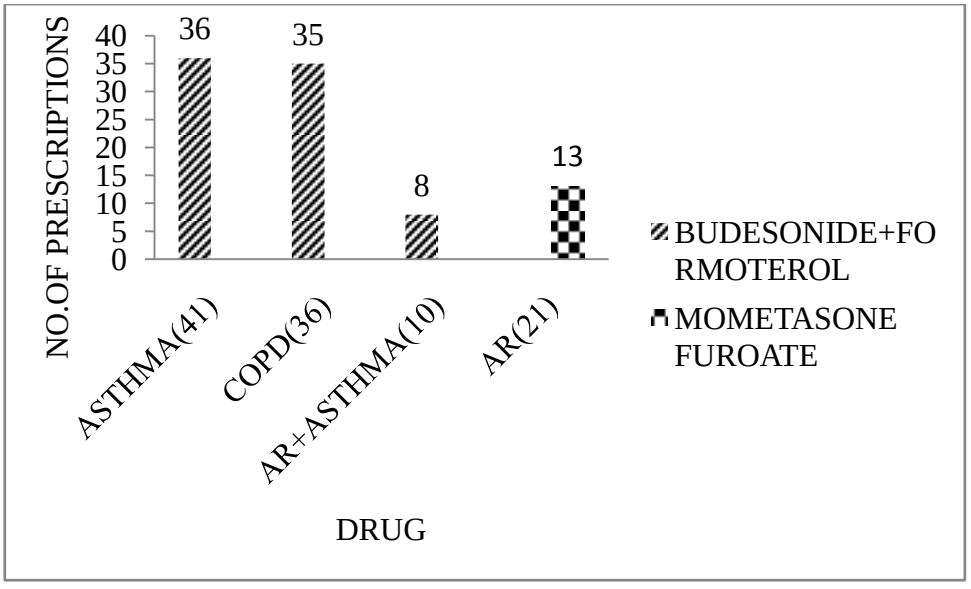


TABLE 15 : Dose wise distribution in the total prescriptions in the Asthma patients.

Sl. No	Budesonide+Formoterol (mcg)	No. of prescriptions	Percentage (%)
1.	200	5	13.88
2.	400	31	86.11

FIGURE 15:Dose wise distribution in the total prescriptions in the Asthma patients.

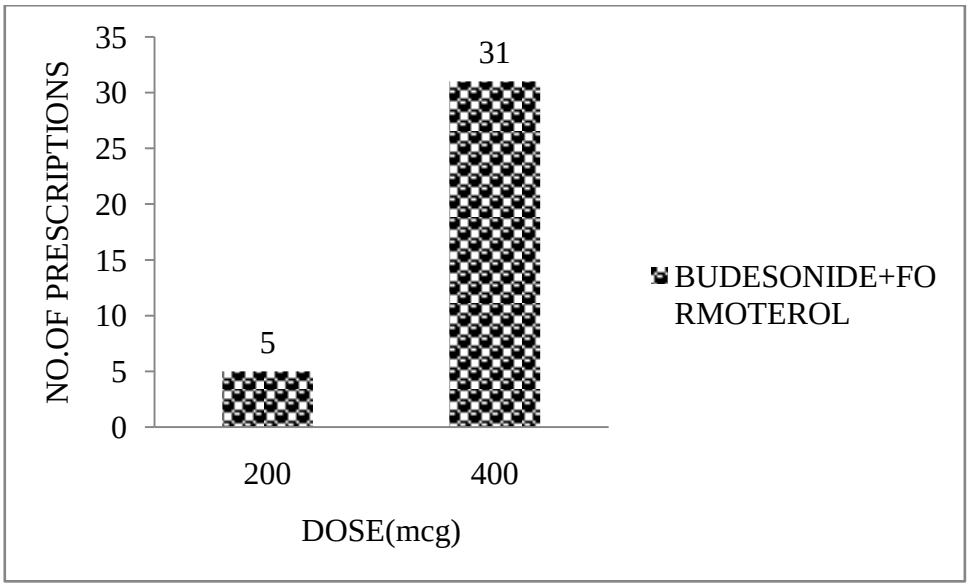


TABLE 16 : Smoking habits of COPD patients (n=36) prescribed with corticosteroids.

Sl. No	Life style	No. of prescriptions	Percentage (%)
1.	Smoker	19	52.77
2.	Ex-smoker	6	16.66
3.	Non-smoker	11	30.55

FIGURE 16 : Smoking habits of COPD patients (n=36) prescribed with corticosteroids.

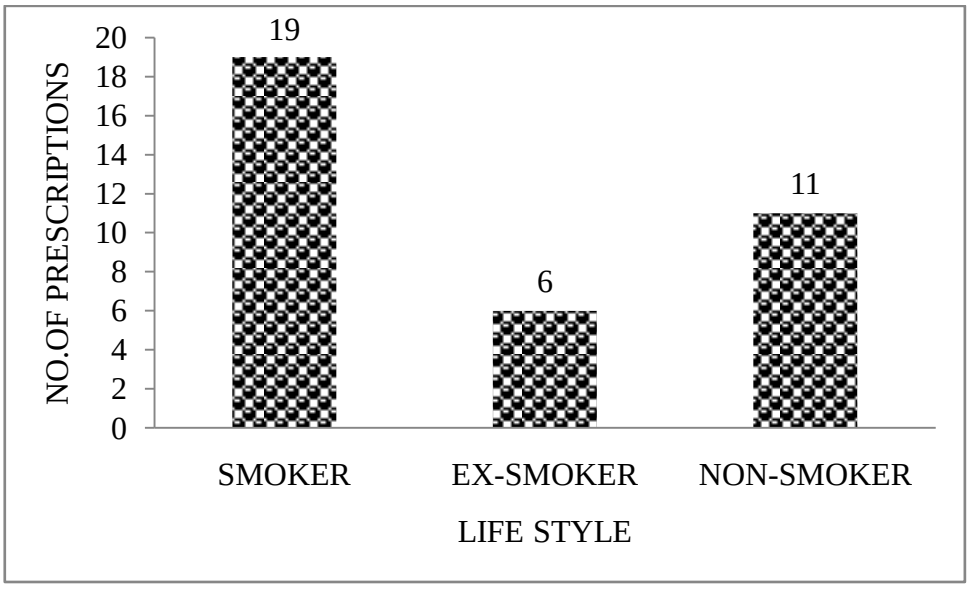


TABLE 17 : Dose wise distribution in the total prescriptions in COPD patients(n=36).

Sl. No	Budesonide+Formoterol (mcg)	No. of prescriptions	Percentage (%)
1.	200	11	31.42
2.	400	24	68.57

FIGURE 17 : Dose wise distribution in the total prescriptions in COPD patients(n=36).

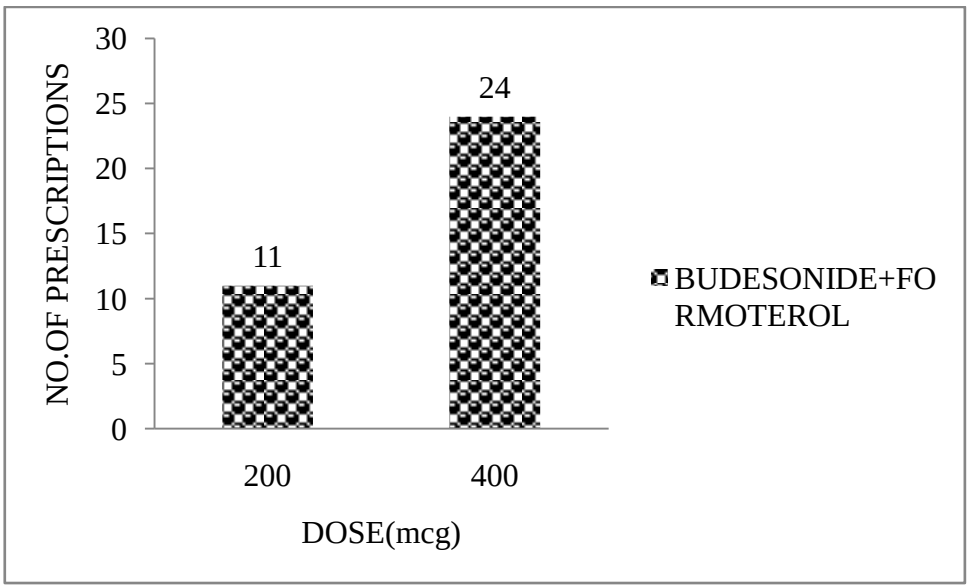


TABLE 18 : Dose wise distribution in the total prescriptions in COPD patients(n=36).

Sl. No	Prednisolone (mg)	No. of prescriptions	Percentage (%)
1.	20	2	40
2.	30	3	60

FIGURE 18 : Dose wise distribution in the total prescriptions in COPD patients(n=36).

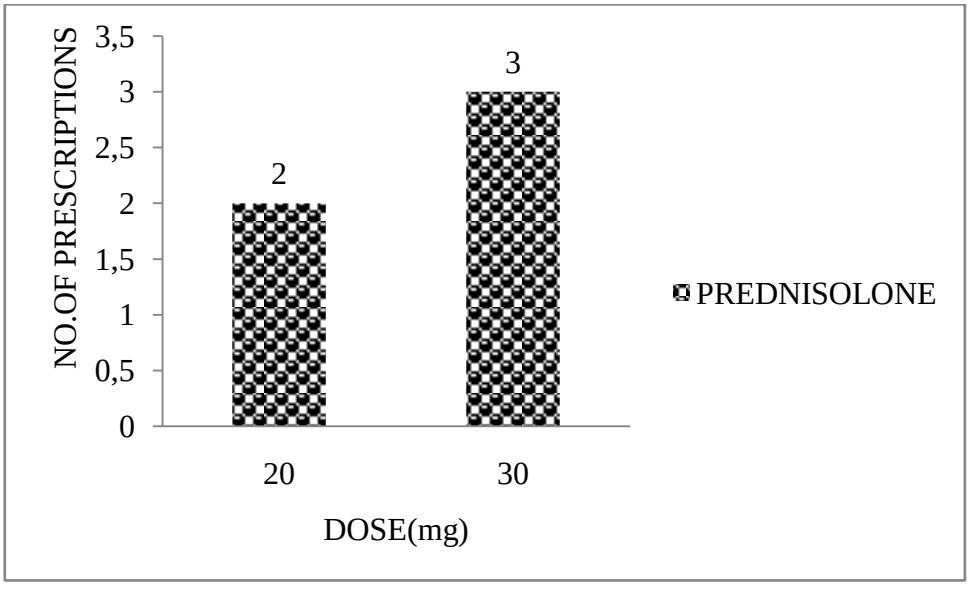


TABLE 19 : Dose wise distribution in the total prescriptions in Allergic Rhinitis patients(n=21).

Sl. No	Budesonide+Formoterol (mcg)	No. of prescriptions	Percentage (%)
1.	200	14	73.68
2.	400	5	26.31

FIGURE 19 : Dose wise distribution in the total prescriptions in Allergic Rhinitis patients(n=21).

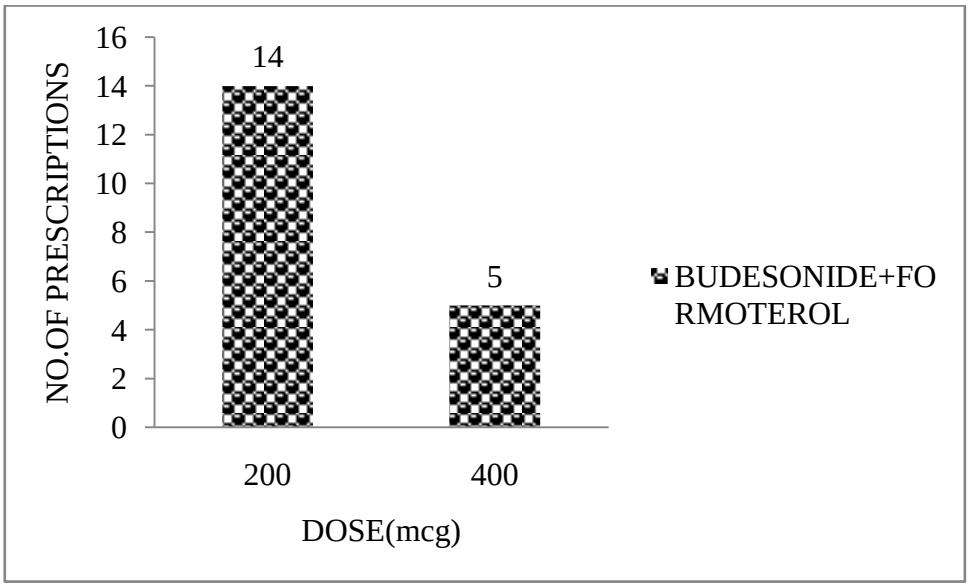


TABLE 20 : Dose wise distribution in the total prescriptions in Allergic Rhinitis +Asthma patients(n=10).

Sl. No	Budesonide+Formoterol (mcg)	No. of prescriptions	Percentage (%)
1.	200	3	37.5
2.	400	5	62.5

TABLE 20 : Dose wise distribution in the total prescriptions in Allergic Rhinitis +Asthma patients(n=10).

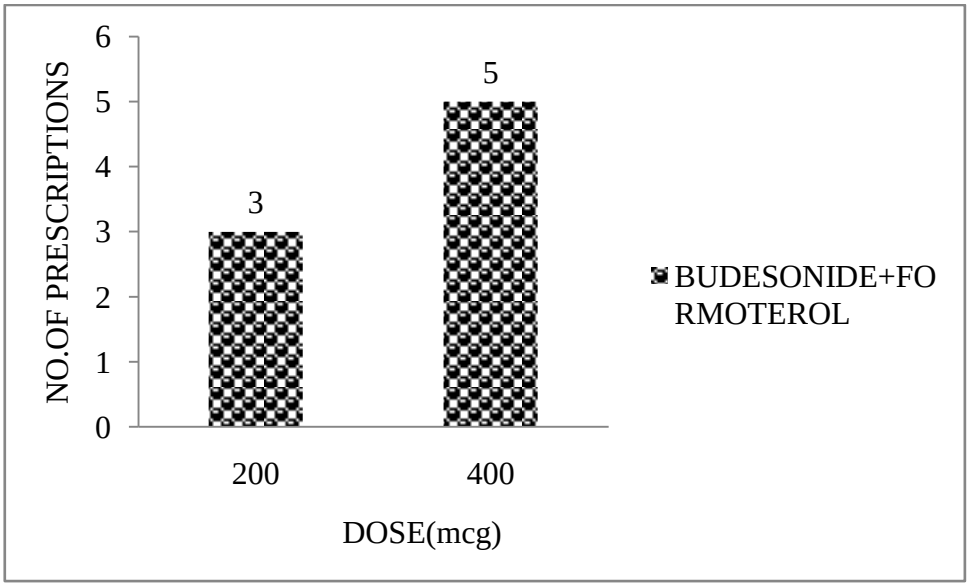


TABLE 21 : Dose wise distribution in the total prescriptions in Allergic Rhinitis +Asthma patients(n=10).

Sl. No	Budesonide (mcg)	No. of prescriptions	Percentage (%)
1.	200	1	50
2.	400	1	50

TABLE 21 : Dose wise distribution in the total prescriptions in Allergic Rhinitis +Asthma patients(n=10).

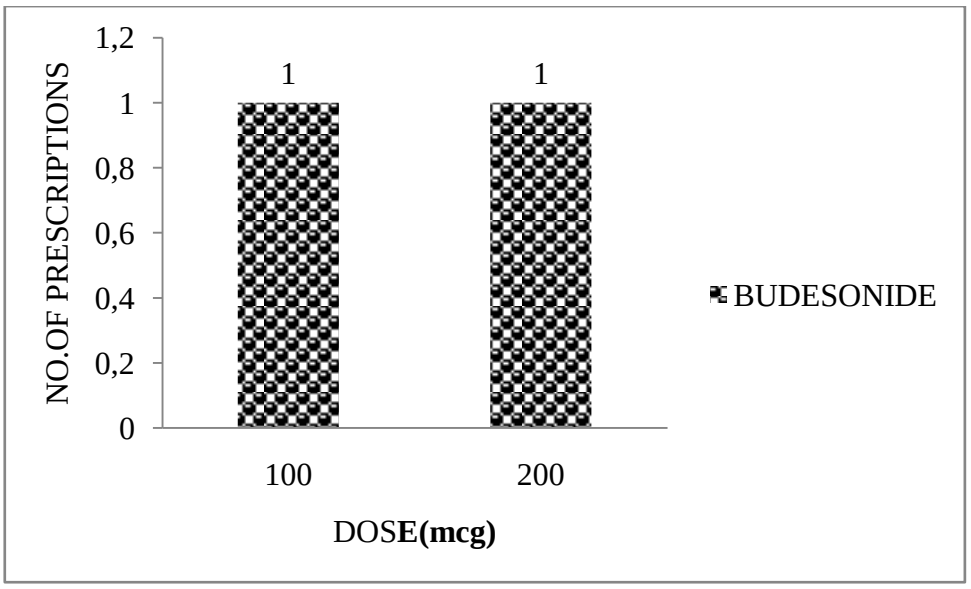


TABLE 22 : Drug wise distribution in the total prescriptions of the IP patients.

Sl. No	Drug	No. of prescriptions	Percentage (%)
1.	Budesonide+Formoterol	13	43.33
2.	Budesonide	9	30
3.	Fluticasone+Salmeterol	1	3.33
4.	Prednisolone	3	10
5.	Hydrocortisone	4	13.33

FIGURE 22 : Drug wise distribution in the total prescriptions of the IP patients.

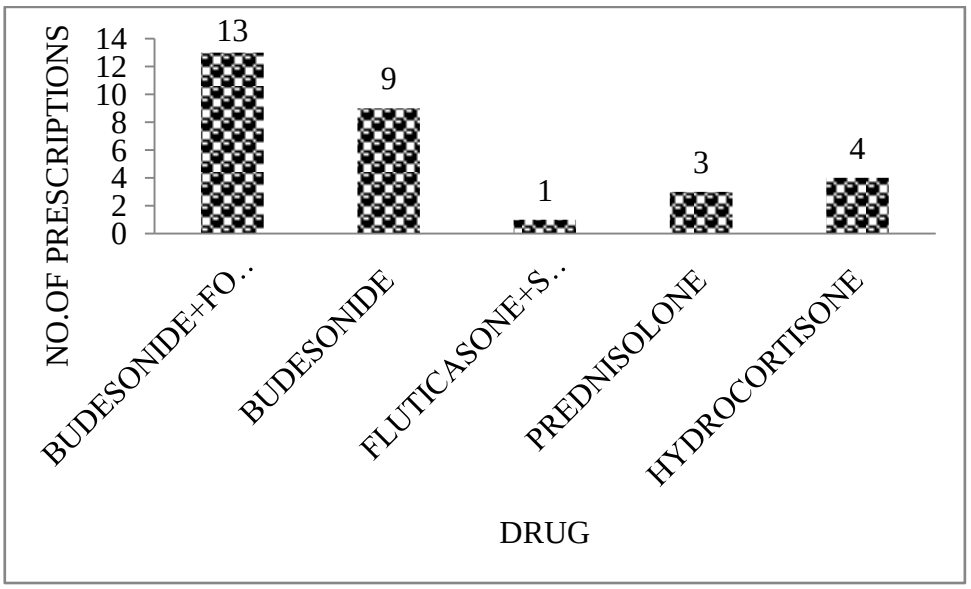


TABLE 23 : Route of administration wise distribution in the total prescriptions of IP patients.

Sl. No	Route	No, of prescriptions	Percentage (%)
1.	MDI	7	23.33
2.	NEB	10	33.33
3.	DPI	6	20
4.	Oral	3	10
5.	Injection	4	13.33

FIGURE 23 : Route of administration wise distribution in the total prescriptions of IP patients.

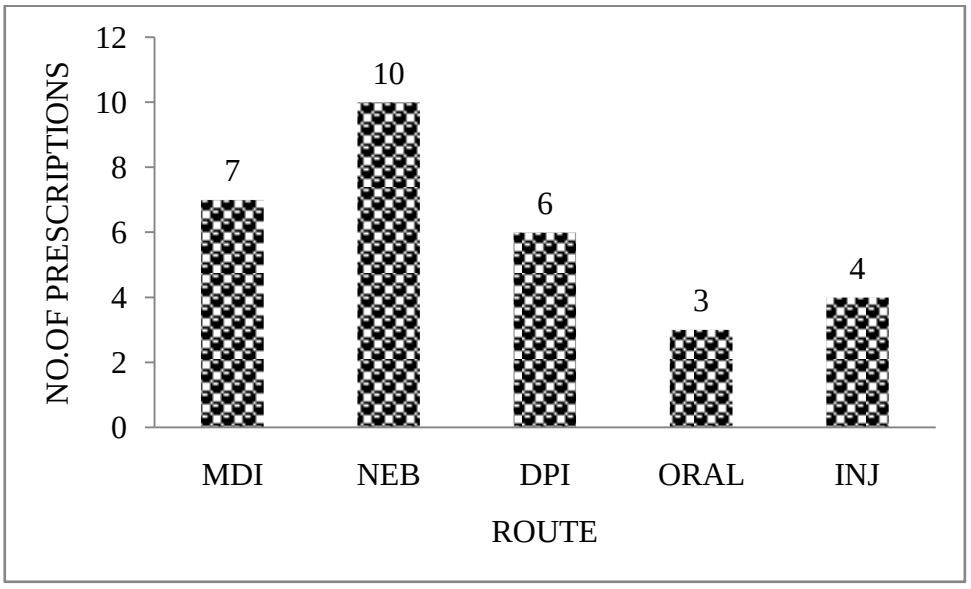


TABLE 24 : Effect of various demographic factors on the prescribing patterns of corticosteroids.

SI NO	PARAMETER	BUDESONIDE+FORMOTEROL	BUDESONIDE	FLUTICASONE+SALMETEROL	MOMETASONE	PREDNISOLONE	P VALUE
1	AGE						
	<50	46	3	3	11	1	<0.007
	>50	52	0	1	2	6	
2	GENDER						
	MALE	58	1	2	2	6	<0.016
	FEMALE	40	2	2	11	1	
3	LOCALITY						
	RURAL	22	2	3	1	1	<0.023
	URBAN	76	1	1	12	6	
4	SOCIO-EC						
	HIGH	12	2	1	7	2	<0.016
	INTER	46	0	2	3	3	
	LOW	40	1	1	3	2	

TABLE 25 : Effect of disease severity on the prescribing patterns of corticosteroids.

SI NO	PARAMETER	BUDESONIDE+FORMOTEROL	BUDESONIDE	FLUTICASONE+SALMETEROL	MOMETASONE	PREDNISOLONE	P VALUE
1	STAGES(COPD)						
	V SEVERE	14			1	1	<0.008
	SEVERE	19			0	1	
	MODERATE	2			0	3	
2	STAGES(ASTHMA)						
	SEVERE	29	0	1		0	<0.011
	MODARATE	7	1	2		2	

Discussion

DISCUSSIONS

Glucocorticoid drugs are maximally utilized in disease related to the respiratory system. Respiratory conditions are usually allergic and inflammatory, where glucocorticoid drugs have a major role to play.

The use of corticosteroid was higher in older people, compared with younger people, may be due to the presence of COPD in older persons. In older persons, these medications are commonly used to treat COPD **(Allbon , 2007)**. However in our study also highest prescriptions were in the older age group.

Different toxic exposures, differences in socioeconomic and living conditions, and differences in education levels also exist and may be responsible, at least in part, for the variations observed in the manifestations of respiratory disease **(Miravitlles et al, 2008).** Interestingly, significant heterogeneity was observed between sites, especially in women **(Buist et al 2007)**. These differences can be observed among different areas of the same country, as was demonstrated in a Spanish study (**Sobradillo et al 2000).** In our study most of the prescriptions containing corticosteroid were made for patients coming from urban and industrial polluted areas.

The use and interpretation of spirometry in primary care (PC) in the diagnosis of chronic obstructive pulmonary disease (COPD) and to identify the treatment schedules administered found out that the number of drugs prescribed increased significantly with severity of the respiratory disease **(Miravitlles et al, 2007).** There was a significant relationship between the disease groups, asthma and COPD, and IC prescription **(Jackevicius et al, 1997)**. In our study also we identified that there was a significant relationship with severity of disease and the prescribed corticosteroids.

The EPOCA study observed significant differences in the characteristics and management of the respiratory disease according to the socioeconomic status of the

patients. It is important to point out the existing limitations for adequate classification of socioeconomic status among different countries. Treatment also showed some differences, with a higher use of old, cheaper, Short-Acting Beta2-Adrenergic Receptor Agonist and theophyllines and a lower use of tiotropium and combination therapy with LABA + ICS in patients of lower class and education **(Miravitlles et al, 2008).** In our study population, we found a significant relationship between socioeconomic status and locality of residence and prescribing patterns of corticosteroids.

Population distribution of asthma medication use identified that females were using more potent inhaled corticosteroids than males. In contrast to the findings in the population as a whole, those who were living in more disadvantaged areas used less potent inhaled corticosteroids **(Allbon , 2007).** In our study we found out that males are using more corticosteroids.

The respiratory medications were being used by COPD and Asthma patients at hospital admission. Most patients used inhaled β-agonists. Other respiratory medications were also used in similar proportions for all groups with the exception of ipratropium bromide. COPD patients were 21/2 times as likely to report the use of anticholinergic agent as asthma patients **(Jackevicius et al, 1997)**. And In our study most common drug prescribed to inpatients was Budesonide + Formoterol combinations 43.33% and less commonly prescribed drug was Fluticasone + Salmeterol 3.33%.

Administration of corticosteroids either orally or by injection can be easily used to control asthma attack. Inhalation therapy is less effective and is not recommended. **(Razi et al, 2002).** And In our study most common route of drug administration prescribed Dry Powder Inhaler (67.2%).

Conclusion

CONCLUSION

Drug use is a complex process. In any country a large number of socio-cultural factors contribute to the way drugs are used. Hence drug utilization research is an essential part of pharmacoepidemiology as it describes the extent, nature and determinants of drug exposure. Drug utilization evaluation can be used for the description of drug use pattern; early signals of irrational use of drugs; interventions to improve drug use; quality control cycle and for continuous quality improvement. For the individual patient, the rational use of a drug implies the prescription of a well documented drug at an optimal dose, together with the correct information, at an affordable price. Drug utilization research in itself does not necessarily provide answers, but it contributes to rational drug use in important ways.

Our study was on the prescribing pattern of the corticosteroids in COPD, Asthma and Allergic Rhinitis in the Pulmonology Department. The present study aims to answer the following questions such as how does the use of corticosteroids vary with demographic factors, like age, sex, socioeconomic status and locality of residence, What are the different types of steroids prescribed, its dose and route of administration, Difference in corticosteroids used in various diseases and how does the use of corticosteroids vary with severity of disease.

In this present study, the first focuses was how the use of corticosteroids vary with the demographic profiles. In the present study focused both men and women in almost equal range and observed that males are more prone to the use of corticosteroids, use was maximum elderly persons. In the study population we find out that there is a statistically significant relationship exist between age ($p<0.007$), gender ($p<0.016$),

locality of residence ($p<0.023$) & socioeconomic status ($p<0.016$) with the prescribing pattern of corticosteroids.

The second priority was given to the different types of steroids prescribed, its dose and route of administration. Most common route of administration was dry powder inhaler (67.2%) followed by MDI (16.8%), Nasal spray (10.4%), and Oral (5.6%) respectively. Most commonly prescribed drug was Budesonide + Formoterol (78.4%)combination whereas Budesonide(2.4%) alone was less commonly prescribed. Budesonide + Formoterol 200 mcg combination was given in 37 prescriptions and 400 mcg was given in 61 prescriptions.

The third focus of the present study is to identify the difference in corticosteroids used in various diseases. In the present study the total study populations were categorized into four group on the basis of diagnosis. It was given as Asthma, COPD, Allergic Rhinitis & Allergic Rhinitis + Asthma. Median route of administration in Asthma , COPD and Allergic Rhinitis +Asthma prescription was dry powder inhaler 33(80.48%), 21(58.33%), 10(60%) respectively. The most prominent route of administration was nasal spray in Allergic Rhinitis prescriptions. Median drug of administration in Asthma, COPD and Allergic Rhinitis +Asthma was Budesonide + Formoterol 36(87.80%) , 35(97.22%), 8(80%) respectively. The most prominent drug of administration was Mometasone furoate 13(61.90%) in Allergic Rhinitis.

The final objective and the focus is to identify that how does the use of corticosteroids vary with severity of disease. Through the present study the investigator is able to recognize that there is a statistical significance in the use of corticosteroids with the severity of diseases like COPD ($p<0.008$) & Asthma ($p<0.011$).

At last, the present study, was able to conclude that the prescription patterns of corticosteroids varied, based on the several factors such as age, sex, socio economic status and area of residence. In the current practice, Dry Powder Inhaler was the most common drug route and the Budesonide + Formoterol the most common prescribed drug of choice among the physicians. The present study also was able to recognize that there is a difference present in the drug prescriptions based on the severity of the disease conditions.

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Appendix

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CERTIFICATE

This is to certify that Mr. Sanoj Varkey , II[nd] year M Pharm (Pharmacy Practice), has done the project entitled as **"PRESCRIBING PATTERNS OF CORTICOSTEROIDS IN PULMONOLOGY DEPARTMENT"** under our supervision at Kovai Medical Center and Hospital, Coimbatore, for the period of 6 months from June to December 2011.

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DATA ENTRY FORM

Name of Patient: …….. **IP No:** ……..…….

Place……. **Age in years**…… **Sex M / F ……**

Married/Unmarried

Occupation: …….

1. **C/O……**

……

…….

2. Socio-Economic Status

Alcohol	**YES**	**NO**	**Ex-Alcoholic**
Smoking	**YES**	**NO**	**Ex-Smoker**

FVC			
FEV_1			
$FEV_1\%FVC$			

3. Past medical history :

…….

…….....

4. Past medication history:

…….....

…….

……..

…….....

5.

DIAGNOSIS……

6. CURRENT MEDICATIONS:

DRUG	DOSAGE	FREQUENCY	DURATION	ROUTE OF ADMINISTRATION

7. DURING THE TREATMENT:

DRUG	DOSAGE	FREQUENCY	DURATION	ROUTE OF ADMINISTRATION